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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,131	04/13/2000	Reynolds Gorsuch	TRANSVI.007A	7531

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EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 07/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

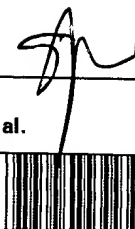
Office Action Summary

Application No.
09/549,131

Applicant(s)
Gorsuch et al.

Examiner
John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above, claim(s) 1-29, 42, 43, 48, and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-41, 44-47, and 50-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. Claims 1-29, 42-43 and 48-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8.
2. Claim 41 is objected to because of the following informalities: A unit for pressure is “mmHg” and not “mm” shown as “5mm” on line 2. Appropriate correction is required.
3. Claims 30-41, 44-47 and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,950,224 (Gorsuch et al ‘224) in view of U.S. Patent No. 5,145,583 (Angleraud et al) and EP 0882494 (EP ‘494). Gorsuch et al ‘224 teach an in-vivo plasma separation method comprising the steps of implanting a filter device in a vein wherein the filter device comprises a plurality of hollow fibers having a pore size of from about 0.1 micron to 1 micron and connected to a catheter and blood plasma passes through the wall of hollow fibers into a hollow center (see figures 1-7; col. 4, line 43 - col. 6, line 68). Claims 30-41, 44-47 and 50-56 essentially differ from the method of Gorsuch et al ‘224 in reciting asymmetrical hollow fiber membrane having a lower mass density at the inner wall surface and a higher mass density at the outer wall surface and the fiber wall structure being a continuous change in mass density from the outer wall to the inner wall and comprising a continuum of voids bounded by solid frames. Angleraud et al teach that asymmetric permeable membranes is used for plasmapheresis wherein pore size is of the order of few tenths of a micrometer and the average size of pores may vary continuously according to the thickness of the membrane in which a separating layer is on the outer wall (see abstract; col. 3, line 68 - col. 4, lines 12; col. 5, lines 15-18). EP ‘494 teaches an

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asymmetric hollow fiber membrane having a lower mass density at the inner wall surface and a higher mass density at the outer wall surface (see figure 1); furthermore, the asymmetric hollow fiber membrane is anisotropic which has a network structure which integrally continues from the inner surface to the outer surface and the average pore diameters in the outer surface becomes gradually greater toward the inner surface of the membrane and the inner surface of the membrane has average pore diameter of 5 micron to 30 microns and outer surface of the membrane has average pore diameter of 0.05 micron or more and less than 1 micron which is suitable for plasmapheresis (see figure 1; page 2, lines 5-6; page 2, line 55 - page 3, line 56). Such gradual increasing pore size from the outer surface to inner surface shows a continuous change in mass density from the outer wall to the inner wall and comprises a continuum of voids bounded by solid frames as shown in figure 1 and furthermore, such structure includes a number of concentric circumferential zones with different mass densities. It would have been obvious to a person of ordinary skill in the art to use the asymmetrical hollow fiber membrane of EP '494 in the plasma separation method of Gorsuch et al '224 by taking particular advantages of asymmetrical permeable membranes as noted by Angleraud et al.

4. Applicant's arguments with respect to claims 30-41, 44-47 and 50-56 have been considered but are moot in view of the new ground(s) of rejection. Applicants argue that the EP '494 does not teach any integral continuation of a network structure from the inner surface to the outer surface, but instead clearly discloses the critical requirement of the inner surface of the fiber having "a three dimensional network structure having thick trunks of 10-30 microns". However,

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EP '494 teaches that "The membrane of the present invention has a shape of a hollow fiber having an inner surface and an outer surface, and comprises a network structure which integrally continues from one surface (e.g., the inner surface) to another surface (e.g. the outer surface) as shown in Fig. 1." See page 3, lines 3-5.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. This application contains claims 1-29, 42-43 and 48-49 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.


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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
July 8, 2003